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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,782	03/30/2001	Thomas Rausch	P/2107-162	7866

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NEW YORK, NY 100368403

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,782

Applicant(s)

RAUSCH, THOMAS

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 February 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 22-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 22-35 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13 and 15-21 have been cancelled and Claims 22-35 have been added.

Applicant's arguments will be addressed to the extent that they read upon newly added Claims 22-35.

Rejection of the Claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendments.

Rejection of the Claims under 35 U.S.C. 101, as being drawn to non-statutory subject matter is withdrawn in view of Applicant's amendments.

The rejections of the Claims under 35 U.S.C. 102 or 103, are withdrawn in view of Applicant's amendments.

Rejection of Claims 15-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-22 of U.S. Patent No. 6,384,300 is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

Claims 22-35 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set

forth in the Official actions mailed 10/23/02. Applicant's arguments filed February 21, 2003 have been considered but are not deemed persuasive.

Applicant asserts that the Examiner's argument that Applicant only teaches the tobacco invertase inhibitor sequence is incorrect given their Rule 132 declaration that a rapeseed invertase inhibitor was isolated and that rapeseed plants transformed therewith showed increased seed storage reserves (response page 4 line 13 to page 5 line 10). Applicant has not described a representative number of genes encoding an apoplastic invertase inhibitor from other species, or described any conserved structural features that are correlated with the function of an apoplastic invertase inhibitor.

Claims 22-35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for tobacco transformed with an isolated tobacco apoplastic invertase inhibitor coding sequence in sense and antisense orientations, bearing seed with altered seed development and reserve content, does not reasonably provide enablement for all plants transformed with any invertase inhibitor coding sequence showing altered seed development and altered reserve content other than in transformed tobacco. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official actions mailed 10/23/02. Applicant's arguments filed February 21, 2003 have been considered but are not deemed persuasive.

Applicant asserts that the Examiner's assertion regarding the unpredictability of enhanced biosynthetic flux through a pathway are not relevant. The Broun reference is cited to show how efforts to increase biosynthetic flux through a pathway were unsuccessful because of unpredicted

Art Unit: 1638

regulatory mechanisms (i.e. increased breakdown or turnover) that limited lysine accumulation. Thus, Applicant's argument that the reserve content of the seed is increased by the inhibition of the regulatory mechanism and not by overexpression is not persuasive (response page 5 line 20 to page 6 line 10). Further, by Applicant's own admission (page 11 line 35 to page 12 line 2 of the specification) there may be unforeseen mechanisms of regulation in a plant. In this case, inhibition of the antisense effect in stamens is likely due to redundant isoforms of the invertase inhibitor protein expressed in those tissues. Unpredictability of this kind would require undue experimentation in attempts to increase reserve material in the claimed non-exemplified species of the invention. Furthermore, Applicant's claim to a sense construct increasing reserve material in the seed of a transformed plant is not supported by the data of the examples.

Applicant asserts that the present invention would require isolation of the protein and determination of amino acid sequences and DNA sequences. Applicant asserts several points to support the argument that the unpredictability of the cited Broun reference is not relevant because the current invention does not rely upon degenerate or non-homologous probes (response page 6 line 18 to page 7 line 5).

First, Applicant asserts that there are publications where the isolation of several invertase inhibitors has been described and that they are available for the present procedure (response page 7 lines 6-8). It should be noted that those sequences are not described in the sequence listing and there is no indication in the specification that those sequences are for apoplastic invertase inhibitors. Nonetheless, the presence of unknown isoforms of the invertase inhibitor poses serious problems for antisense reduction of the expression of the invertase inhibitor; especially

so, considering Applicant is now broadly claiming sequences that have 80% sequence identity to sequences isolated from young ovules of any plant.

Second, Applicant asserts that isolation of the protein would exclude use of primers or probes that are not 100% homologous. This is incorrect since Applicant claims isolation of an invertase inhibitor protein as a means of obtaining the gene (response page 7 lines 9-14), and since the amino acids comprising the inhibitor protein can be encoded by any one of several corresponding redundant codons, there is an element of unpredictability when isolating homologous or near homologous sequences of the invention for use in antisense inhibition.

Third, Applicant asserts that the message is obtained from the flowers with young ovules and fourth, that the family of invertase inhibitor genes have limited homology to themselves and sequences encoding proteins that inhibit pectin methyl esterase (response page 7).

The Examiner responds that primers or probes based upon the amino acid sequence, required for isolation of the DNA sequences of other apoplastic invertase inhibitors, require back translation through the codon table which is degenerate and would have reduced homology to the native gene. Further, Applicant has not isolated the exemplified tobacco and rapeseed DNA sequences encoding an apoplastic invertase inhibitor using the method of isolating a protein. Rather, Applicant has isolated a cDNA by some undescribed means from a cell suspension culture of tobacco and not from the ovules of young tobacco flowers. Furthermore, the Rule 132 declaration submitted describing the transformation of rapeseed with an apoplastic invertase inhibitor does not indicate any protein isolation whatsoever, rather the gene of interest was isolated using a different method from that of instant claims, i.e. using a *Brassica* homolog from *Arabidopsis*. In addition, since the declaration demonstrates the isolation of RNA from young

fruits, while the instant specification only provides guidance for the isolation of a sequence derived from a cell suspension culture, the declaration does not utilize the teachings of the specification, and so cannot be relied upon for the enablement of multiple gene sequences. Finally, the declaration supports the Examiner's position that the method would only work when a particular plant species is transformed with an invertase inhibitor gene from the same species.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
May 13, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

David T. Fox